

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Roger R. C. New

Serial No.: 10/553,169

Filed: April 15, 2004

For: UPTAKE OF MACROMOLECULES

DECLARATION

I, Roger R. C. New, do hereby declare and state as follows:

I am the inventor for US Serial No. 10/553,169 and have a thorough knowledge of the invention.

In the Office Action that issued on this application with a mail date of 5 August 2008 the Examiner suggests that it would have been obvious to add propyl gallate (PG) or butyl hydroxyl anisole (BHA) to a composition as described in the prior art document US 5,853,748. The compositions described in US 5,853,748 contain, *inter alia*, a bile acid or salt together with an agent with the ability to adjust the pH in the gut to a value of from 7.5 to 9. A preferred bile acid used in US 5,853,748 is chenodeoxycholate. A preferred pH adjuster used in US 5,853,748 is sodium bicarbonate.

I have conducted experiments to investigate whether or not it is actually possible to prepare a clear aqueous solution containing, along with chenodeoxycholate, both (i) sodium bicarbonate, and (ii) either PG or BHA.

First, I took a solution of 78.1mg chenodeoxycholate and 36.9mg PG in 1mL water and added 37.8mg sodium bicarbonate to it. The amounts of chenodeoxycholate and PG were chosen so as to replicate closely the 2:1 weight ratio that is used in the Examples of US Patent Application No. 10/553,169. The amount of sodium bicarbonate relative to the amount of chenodeoxycholate was chosen so as to replicate closely the 1:2 weight ratio that is used in Example 4 of US 5,853,748. An insoluble

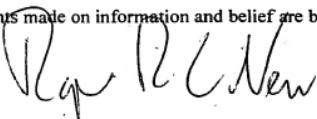
mixture resulted. More specifically, a turbid dispersion was formed and even after incubation at 60°C it was still not possible to achieve a clear aqueous solution. Upon continued incubation for one hour at 37 °C, the mixture remained cloudy. Comparing this to an equivalent experiment wherein no sodium bicarbonate was added the difference was very marked throughout. In particular, the mixture without sodium bicarbonate formed a completely clear solution.

Second, I took a solution of chenodeoxycholate and sodium bicarbonate and added PG to it. The same amounts of the components were used as in the first experiment. A turbid dispersion was formed and even after incubation at 60 °C it was still not possible to achieve a clear aqueous solution.

Third, I conducted the first two experiments again but with the same weight of BHA in place of the PG. Similar results were obtained, i.e. a turbid dispersion was formed and no clear aqueous solutions were obtainable even after incubation at 60°C.

Finally, I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, and may jeopardize the validity of the application or any patent issuing thereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Signed

  
Ray D. New

This 2<sup>nd</sup> Day of April, 2009